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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,571	09/11/2001	Kenneth R. Chien	6627-PA0123	7236

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BROWN, MARTIN, HALLER & MCCLAIN LLP
1660 UNION STREET
SAN DIEGO, CA 92101-2926

EXAMINER
PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,571	CHIEN ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 23-27, drawn to a method for delivering a therapeutic does of a gene expression cassette in a fluid selectively to heart for sustained expression, wherein the gene of interest is a structural gene, classified in classes 514 and 424, subclasses 44 and 93.2.

II. Claims 28-30, drawn to a method for delivering a therapeutic does of a gene expression cassette in a fluid selectively to heart for sustained expression, wherein the gene of interest is a functional gene, classified in classes 514 and 424, subclasses 14 and 93.2.

III. Claims 32-40, drawn to a method for delivering a therapeutic does of a gene expression cassette in a fluid selectively to heart for sustained expression, wherein the gene of interest is a mutated form of a gene, classified in classes 514 and 44, subclasses 14 and 93.2.

Claims 1-22 and 31 link(s) inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-22 and 31. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to

examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I, II and III are distinct each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods, which are not capable of use together, as they appear to have different efffects. In particular, the methods of Groups I-III comprise materially different products, which appear to have different functions. More particularly, the different products are genes of interest that encode different protein products, which appear to have different functions when expressed in the heart. Groups I-III comprise genes of interest that are from different classes of genes. For example, the methods of Group I embrace use of structural genes, the methods of Groups II embrace use of functional genes, and the methods of Groups III embrace use of mutated genes. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

It is noted that the Group I claims comprise methods for delivering a therapeutic does of a gene expression cassette to heart that require the use of different structural genes. If the Group I claims are elected, further restriction to a particular structural gene will be required as follows:

Claims 23-27 are generic to a plurality of disclosed patentably distinct species of treatment methods requiring the use of different structural genes:

A. α-sarcogylcan

B. β-sarcogylcan

C. γ-sarcogylcan

D. δ-sarcogylcan

Patentably distinct methods for treating the heart comprising distinct therapeutic structural genes are encompassed by the claims. A specific member of an elected species of structural gene should be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from one of groups A-D, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

It is noted that the Group II claims comprise methods for delivering a therapeutic does of a gene expression cassette to heart that require the use of different functional genes. If the Group II claims are elected, further restriction to a particular structural gene will be required as follows:

Claims 28-30 are generic to a plurality of disclosed patentably distinct species of treatment methods requiring the use of different functional genes:

A. β-adrenergic receptor (β-AR)

B. Ca^{2+} ATPase (SERCA-2)

Patentably distinct methods for treating the heart comprising distinct therapeutic functional genes are encompassed by the claims. A specific member of an elected species of functional gene should be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from one of groups A-B, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

It is noted that the Group III claims comprise methods for delivering a therapeutic does of a gene expression cassette to heart that require the use of different mutated genes. If the Group III claims are elected, further restriction to a particular mutated gene will be required as follows:

Claims 32-40 are generic to a plurality of disclosed patentably distinct species of treatment methods requiring the use of different mutated genes:

A. A dominant negative form of PLB containing a mutation at amino acid 2 from glutamic acid (E) to alanine (A).

B. A dominant negative form of PLB containing a mutation at amino acid 14 from arginine (R) to glutamic acid (E).

C. A dominant negative form of PLB containing a mutation at amino acid 16 from serine (S) to asparagine (N).

D. A dominant negative form of PLB containing a mutation at amino acid 16 from serine (S) to glutamic acid (E).

E. A dominant negative form of PLB containing a mutation at amino acid 49 from valine (V) to alanine (A).

F. A dominant negative form of PLB containing a mutation at amino acid 3 from Lysine (K) to glutamic acid (E) and at amino acid 14 from arginine (R) to glutamic acid (E).

G. any one of a dominant negative form of PLB listed in (A-F) in conjunction with a SERCA-2 gene.

Patentably distinct methods for treating the heart comprising distinct therapeutic mutated genes are encompassed by the claims. A specific member of an elected species of mutated gene should be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from one of groups A-G, even though this requirement is traversed.
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition, it is noted that claims 1-6, which are generic to all groups, comprise methods embracing distinct steps for increasing the dwell time of fluid in a targeted area of the heart. Accordingly, further restriction to a particular step for increasing the dwell time of a fluid is required.

Claims 1-6 are generic to a plurality of disclosed patentably distinct species of treatment methods requiring different steps for increasing dwell time of a fluid:

A. Induction of hypothermia

B. Isolation of the heart from systemic circulation

C. Induction of hypothermia and isolation of the heart from systemic circulation

D. Induction of complete or near-complete transient cardiac arrest

E. Induction of reversible bradycardia

Patentably distinct methods for treating the heart comprising distinct steps for increasing the dwell time of a fluid are encompassed by the claims. A specific member of an elected species of step for increasing the dwell time of a fluid should be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from one of groups A-E, even though this requirement is traversed.
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Finally, it is noted that claim 7, which is generic to all groups, comprise methods embracing distinct vascular permeabilizing agents. Accordingly, further restriction to a particular vascular permeabilizing agent is required.

Claim 7 is generic to a plurality of disclosed patentably distinct species of treatment methods requiring different vascular permeabilizing agents:

A. Histamine

B. Substance P

C. Serotonin

Patentably distinct methods for treating the heart comprising distinct steps for increasing the dwell time of a fluid are encompassed by the claims. A specific member of an elected species of step for increasing the dwell time of a fluid should be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from one of groups A-E, even though this requirement is traversed.
Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER